**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Sebastian ROSE and Dominique KLEIN

U.S. Serial No.: 10/541,527

Group Art Unit: not yet assigned

U.S. Filing Date: not yet known

Examiner: not yet assigned

For: METHOD FOR PREPARING METHYL 2-DIPHENYLMETHYSULFINYLACETATE

EXPRESS MAIL LABEL NO: EV 482612215 US DATE OF DEPOSIT: February 28, 2006

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

EV48567557272

Sir:

### RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS

In response to the "Notification of Missing Requirements", dated January 6, 2006, applicant submits herewith, a copy of such notice. The required items, namely the executed Declaration/Power of Attorney, Preliminary Amendment, and appropriate surcharge were previously submitted on October 27, 2005. A copy of the previously filed .documents are enclosed.

Respectfully submitted,

Date: February 28, 2006

S. Maurice Valla

Registration No. 43,966

WOODCOCK WASHBURN LLP One Liberty Place - 46th Floor Philadelphia PA 19103 Telephone: (215) 568-3100

IAP3 Rec'd PCT/PTO 28 FEB 2006

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	PTO-1390			ATTORNEY DOCKET NUMBER CEPF-0007	
U.	S. DEPAK	TMENT OF COMMERCE PA	TENT AND TRADEMARK OFFICE	CEFF-0007	
`	$\mathbf{D}^{1}$	NSMITTAL LETTER TO ESIGNATED/ELECTED	OFFICE (DO/EO/US)	U.S. APPLICATION NO. (if known see 37 CFR 1.5) 10/521,527	
- marib		ONCERNING A FILING			
	NATION 32004/00	IAL APPLICATION NO. 0002	INTERNATIONAL FILING DATE 08 January 2004 (08.01.2004)	PRIORITY DATE CLAIMED   13 January 2003 (13.01.2003)	
TITLE	OF INVE	ENTION METHOD FOR P	REPARING METHYL 2-DIPHENYL	METHYLSULFINYLACETATE	
			ROSE and Dominique KLEIN		
Applica informa		ith submits to the United Stat	tes Designated/Elected Office (DO/EO/L	JS) the following items and other	
1. 2. 3. 4. 5.		This is a SECOND or SUB This is an express request to include items (5), (6), (9), a The US has been elected (A A copy of the International a is attached hereto (b has been communi	and (21) indicated below.	ming a filing under 35 U.S.C. 371. s (35 U.S.C. 371(f)). The submission must 2)). he International Bureau).	
<ul><li>6.</li><li>7.</li></ul>	An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).  a.				
8.		An English translation of the	e amendments to the claims under PCT	Article 19 (35 U.S.C. 371(c)(3)).	
9.	$\boxtimes$	An oath or declaration of the	e inventor(s) 35 U.S.C. 371(c)(4).		
10.		An English translation of the (35 U.S.C. 371(c)(5)).	e annexes to the International Preliminar	ry Examination Report under PCT Article 36	
Items 1	l. to 20. l	below concern other docum	nent(s) or information included:		
11.		An Information Disclosure S	Statement under 37 CFR 1.97 and 1.98.	11 on a mid- 27 CED 2 29 and 2 21 in	
12.		An assignment document fo included.	r recording. A separate cover sneet in co	compliance with 37 CFR 3.28 and 3.31 is	
13.	$\boxtimes$	A preliminary amendment.	·.		
14.		An Application Data Sheet	under 37 CFR 1.76.		
15.		A substitute specification.		•	
16.		A power of attorney and/or of	change of address letter.	1 - cmp 1 10 0 105 CMP 1 100	
17.			of the sequence listing in accordance with	h PCT Rule 13 <i>ter</i> .2 and 37 CFR 1.182-	
18. 19. 20.	1.825.  A second copy of the published international application under 35 U.S.C. 154(d)(4).  A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).  Other items or information: - a return postcard.  EV4825325US				
		- a return postcard.			
			EXPRESS MAIL Mail	ing Label No. EV 482612325 US	

EXPRESS MAIL Mailing Label No. EV 482612325 U. Date of Deposit: October 27, 2005



PTO-1390 (Rev. 07-2005)

Approved for through 3/31/2007. OMB 0651-0021
U.S. Patent and Tradem fice; U.S. Department of Commerce
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid IMB control number.

U.S. APPLICATION NO 10/541,527	. (if known 37 C.F.R. 1.5)	ATTORNEY DOCK CEPF-0007	ET NUMBER		
The following fees are	submitted:				
	I fee (37 CFR 1.492(a)		\$300	\$	
22. Examination	fee (37 CFR 1.492(c))			\$	
If written opinion prep	ared by ISA/US or the	international preliminary ex	amination report		<u> </u>
prepared by IPEA/US:	indicates all claims sat	isfy provisions of PCT Artic			
All other situations	•		\$0.00 \$200	\$	
23. Search fee	(37 CFR 1.492(b))			0.00	
If the written opinion o	f the ISA/US or the Inte	ernational preliminary examina	tion report		
prepared by IPEA/US in	idicates all claims satisf	fy provisions of PCT Article 33	3(1)-(4) \$0		
USPTO as an Internation	onal Searching Author	id on the international application	\$100	\$	•
International Search Re	enort prepared by an I	SA other than the US and pro	•		·
Office or previously co			\$400		
All other situations			\$500		
TOTAL of 21, 22 and	23 =			\$	
Additional fee for	specification and draw	rings filed in paper over 100	heets		•
(excluding sequence lis	sting in compliance wi	th 37 CFR 1.821(c) or (e) or	computer		
program listing filed in	electronic medium) (	37 CFR 1.492(j)).			
The fee is \$250 for each	h additional 50 sheets	of paper or fraction thereof.			
		Number of each additional			
Total Sheets	Extra Sheets	50 or fraction thereof (round RATE up to a whole number)			
- 100 =	/50=	up to a whole number)	X \$250	\$	
Surcharge of \$130.00 f		ne search fee, or the oath or d		\$130.00	
		age (37 CFR 1.492(h)).			
Claims	Number Filed	Number Extra	Rate		
Total claims	31- 20 =	11	X \$50	\$550.00	
Independent Claims	1-3=	0	X \$200	. \$	
Multiple dependent cla	ims(s) (if applicable)		+ \$360	\$	·
		TOTAL OF ABOVE CAL	CULATIONS =	\$680.00	
Applicant claims sr reduced by ½.	nall entity status. See	\$			
		\$680.00			
Processing fee of \$130 the earliest claimed pri	.00 for furnishing the lority date (37 CFR 1.4	\$			
		\$680.00	<u> </u>		
Fee for recording the e	nclosed assignment (3	•	· .		
accompanied by an app	00000				
		TOTAL FEES	ENCLOSED =	\$680.00	<b>\$</b>
				Amount to be: refunded	. 3
03/06/2006 ATRAN1 000	00168 233050 1054158	Amount to be	\$		
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02 FC:1615 550.00	3 7.0			·	

	the following
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PTO-1390 (Rev. 07-2005)

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U.S. Patent and Trademan ce; U.S. Department of Commerce
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a.	$\boxtimes$	A check in the amount of \$680.00 to cover the above fee is enclosed.
b.		Please charge my Deposit Account No. 23-3050 in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.
c.	$\boxtimes$	The Commissioner if hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23-3050. A duplicate copy of this sheet is enclosed.
(b)	) mu	Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or set be filed and granted to restore the application to pending status.  ALL CORRESPONDENCE TO:  SIGNATURE
Wo On Phi	odco e Lib ladel	e E. Miller ck Washburn LLP erty Place - 46th Floor phia, PA 19103 8-3100  S. Maurice Valla NAME  43,966 REGISTRATION NUMBER

**PATENT** 

DOCKET NO.: CEPF-0007 Application No.: 10/541,527

Office Action Dated: Preliminary Amendment

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation No.: Not Yet Assigned

Sébastien Rose, et al.

Group Art Unit: Not Yet Assigned

Application No.: 10/541,527

Int. App. No.: PCT/IB2004/000002

Int. Filing Date: 08 January 2004

Examiner: Not Yet Assigned

U.S. Filing Date: Not Yet Known

METHOD FOR PREPARING METHYL 2-**DIPHENYLMETHYLSULFINYLACETATE** 

EXPRESS MAIL LABEL NO: EV 482612325 US

DATE OF DEPOSIT: October 27, 2005

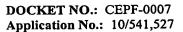
Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

### PRELIMINARY AMENDMENT

Con	nsideration is respectfully requested in view of the ame	endments and/or remarks as
indicated be	elow:	
	Amendments to the Specification begin on page	2 of this paper.
$\boxtimes$	Amendments to the Claims are reflected in the lipage 3 of this paper.	sting of the claims which begins or
	Amendments to the Drawings begin on page attached replacement sheet.	of this paper and include an
$\square$	Remarks begin on page 7 of this paper.	





Office Action Dated: Preliminary Amendment

Please amend the Specification as follows:

At page 1, after the title, please insert the following:

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application represents entry into the U.S. national phase of International

Application No. PCT/IB2004/000002, filed January 8, 2004, which in turn claimed priority
of European Application No. EP 03290082.1, filed January 13, 2003.

### FIELD OF THE INVENTION

At page 1, line 4, please insert the following before the paragraph beginning "MDMSA ...":

### BACKGROUND OF THE INVENTION

At page 1, line 17, please insert the following before the paragraph beginning "These aims ...":

### SUMMARY OF THE INVENTION

At page 1, line 25, please insert the following before the paragraph beginning "Scheme 1 ...":

<u>DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS</u>



DOCKET NO.: CEPF-0007 Application No.: 10/541,527

Office Action Dated: Preliminary Amendment

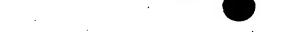
**PATENT** 

This listing of claims will replace all prior versions, and listings, of claims in the application.

### **Listing of Claims:**

1. (Original) Method for preparing methyl 2-diphenylmethylsulfinylacetate (MDMSA) comprising the steps of :

- (i) conversion of benzhydrol into methyldiphenylmethylthio-acetate; and
- (ii) conversion of methyldiphenylmethylthioacetate into methyl-2-diphenylmethylsulfinylacetate.
- 2. (Original) Method according to claim 1, in which step (i) comprises the following steps:
  - a1) conversion of benzhydrol to benzhydrol carboxylate in an appropriate solvent;
  - b1) conversion of the benzhydrol carboxylate to methyl diphenylmethylthioacetate.
- 3. (Original) Method according to claim 2, in which the step (a1) comprises reacting benzhydrol and an acid anhydride in the presence of an inorganic acid and in an appropriate solvent.
- 4. (Original) Method according to claim 3, in which the solvent is an aprotic solvent.
- 5. (Original) Method according to claim 4, in which the aprotic solvent is chosen from chlorinated solvents, aromatic solvents, hydrocarbon solvents and ethereal solvents.
- 6. (Original) Method according to claim 5, in which the aprotic solvent is chosen from chlorinated solvents.
- 7. (Original) Method according to claim 6, in which the solvent is dichloromethane.



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8. (Currently amended) Method according to any one of claims 3 to 7 claim 3, in which the acid anhydride is chosen from acetic anhydride, propanoic anhydride and butyric anhydride.

- 9. (Original) Method according to claim 8, in which the acid anhydride is acetic anhydride.
- 10. (Currently amended) Method according to any one of claims 3 to 9 claim 3, in which the inorganic acid is chosen from hydrochloric acid, butyric acid, o-phosphoric acid and sulfuric acid.
- 11. (Original) Method according to claim 10, in which the inorganic acid is sulfuric acid.
- 12. (Currently amended) Method according to any one of claims 3 to 11 claim 3, in which the quantity of inorganic acid used is from 0.02 to 0.3 molar equivalents relative to the benzhydrol.
- 13. (Currently amended) Method according to any one of claims 3 to 12 claim 3, in which the reaction temperature in step a) is between –5°C and +5°C.
- 14. (Currently amended) Method according to claim 2 to 13, in which step b1) comprises bringing the solution obtained in step a) into contact with methyl thioglycolate.
- 15. (Original) Method according to claim 14, in which the contact time used in step b1) is between 2 and 3 hours.
- 16. (Currently amended) Method according to claim 14 to 15, in which the contact temperature used in step b1) is between 15°C and 25°C.



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- 17. (Currently amended) Method according to any one of the preceding claims claim 1, in which the oxidizing agent is chosen from oxone, potassium permanganate, sodium percarbonate, peroxides such as hydrogen peroxide, tert-butyl hydroperoxide and m-chloroperoxybenzoic acid.
- 18. (Original) Method according to claim 17, in which the oxidizing agent is hydrogen peroxide.
- 19. (Original) Method according to claim 18, in which the hydrogen peroxide is added in the form of a 35% aqueous solution.
- 20. (Currently amended) Method according to any one of the preceding claims claim 1, in which the oxidizing agent is used in an amount of 1 to 1.1 molar equivalent.
- 21. (Currently amended) Method according to any one of the preceding claims claim 1, in which the reaction temperature in step (ii) is between 28°C and 37°C.
- 22. (Currently amended) Method according to ene of claims 3 to 21 claim 3, in which an additional quantity of inorganic acid is added in step (ii).
- 23. (Original) Method according to claim 22, in which the additional quantity of inorganic acid is from 0.02 to 0.3 molar equivalents.
- 24. (Currently amended) Method according to either of claims 22 and 23 claim 22, in which the contact time in step (ii) is between 10 and 13 hours.
- 25. (Currently amended) Method according to any one of the preceding claims claim 1, which comprises an additional step (iii) recovering the methyl 2-diphenylmethylsulfinylacetate obtained.



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- 26. (Original) Method according to claim 25, in which step (iii) comprises a distillation of the solvent to dryness.
- 27. (Currently amended) Method according to any one of claims 25 to 26 claim 25, in which step (iii) comprises a step of direct crystallization.
- 28. (Original) Method according to claim 27, in which the crystallization solvent is chosen from methanol, ethanol, ethyl acetate, isopropyl acetate and toluene.
- 29. (Original) Method according to claim 28, in which the crystallization solvent is isopropyl acetate.
- 30. (Currently amended) Method according to any one of the preceding claims claim 1, in which the successive steps are carried out in the same reactor without isolation of the intermediate compounds.
- 31. (Currently amended) Method for preparing modafinil comprising preparing MDMSA according to claims claim 1 to 30.



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Office Action Dated: Preliminary Amendment

**PATENT** 

### **REMARKS**

After entry of the instant amendment, claims 1 to 31 will be pending. Claims 8, 10, 12-14, 16, 17, 20-22, 24, 25, 27, 30 and 31 are amended herein.

The specification and claims have been amended to remove improper multiple dependencies and to comply with U.S. practice. No new matter is added.

An early action on the merits is requested respectfully.

Date: October 27, 2005

S. Maurice Valla

Registration No. 43,966

Woodcock Washburn LLP One Liberty Place - 46th Floor Philadelphia PA 19103

Telephone: (215) 568-3100 Facsimile: (215) 568-3439



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re Application	of:		·			
For: METHOD FOR I	PREPARING METHYL 2-D	IPHENYLME	THYLSULF:	INYLACETA	re	
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	DECLARATION ANI	) POWER	OF ATTO	DRNEY		
As a below named in	nventor, I hereby declar	e that:				
	TYPE OF I	DECLARA	TION	. •		
	1112			•		
This declaration is fo	or the following type of	application				
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[ Original			Divis	ional	٠.	
Continuation		X	U.S. 1	National Sta	ige of Po	CT
Continuation						
	office address and citize coriginal, first and sole nt inventor (if plural na hich a					
	Utility Patent	Des	sign Paten	t		
is sought on the inve	ntion, whose title appea	rs above, th	e specific	ation of wh	ich:	
	is attached hereto	٠.				•
	was filed on		as	U.S. Appl	lication	Numbe
	ond was amen	ded on	(if appl	icable)		

was described and claimed in PCT International Application Number PCT/IB04/000002, filed on 8/1/04and as amended under PCT Article 19 on and/or PCT Article 34 on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to the patentability of this application in accordance with 37 CFR § 1.56.

# DISCLOSURE AND/OR CLAIM FOR PRIORITY UNDER 35 U.S.C. §§ 119(a)-(d) OF FOREIGN APPLICATIONS FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) OF THIS APPLICATION

I hereby claim foreign priority benefits under Title 35, United States Code §§ 119(a)-(d) of any foreign applications for patent, inventor's certificate or PCT international application designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent, inventor's certificate or any PCT international application designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

Yes   Yes   Yes   Yes   Yes	Country	Application Number	Date of Filing (day, month, year)	Prio Und	rity Cla er 37 U	imed SC § 11	9a-
Yes	(or indicate if ICI)	T various			Yes		N
					Yes		N
					Yes		N
Yes					Yes		N

## DISCLOSURE OF FOREIGN APPLICATION(S) IF ANY, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THE FILING OF THIS APPLICATION

Country (or indicate if PCT)	Application Number	Date of Filing (day, month, year)
EUROPE	03290082.1	13.01.03
		·

DOCKET NO.: CP 244	- 3 -	PATENT
		·

# CLAIM FOR PRIORITY OF UNITED STATES APPLICATIONS OR PCT APPLICATIONS FILED IN THE UNITED STATES RECEIVING OFFICE UNDER 35 U.S.C. § 120

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Date Filed	Status Patented/Pending/Abandone
i.	

## CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) UNDER 35 U.S.C. § 119(e)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

	I must be the
Provisional Application No.	Filing Date
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· · · · · · · · · · · · · · · · · · ·	
	•

### POWER OF ATTORNEY

I hereby appoint all the practitioners associated with Customer 46347 to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected therewith. Each practitioner associated with Customer Number 46347 is an attorney registered before the United States Patent and Trademark Office.

Address all telephone calls and correspondence to:

Suzanne E. Miller, Esq. at the address associated with Customer No. 46347

Telephone No.: (215) 568-3100 Facsimile No.: (215) 568-3439

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of

first joint inventor

ROSE

Sébastien (Given Name)

(Middle Initial or Name)

(Family or last name)

City/State of Actual Residence: ARSY - FRANCE

Mailing Address: 23, chemin du Tour de Ville - 60190 ARSY - FRANCE

Country of Citizenship: FRENCH

Inventor's signature:

Date: 20/07/05

Full	name	of second	inventor
_			

Dominique

(Given Name)

(Middle Initial or Name)

KLEIN (Family or last name)

City/State of Actual Residence: MAURECOURT - FRANCE

Mailing Address: 28, rue Itasse - 78780 MAURECOURT - FRANCE

Country of Citizenship: FRENCH

Inventor's signature:

Date: 20/07/05



23377

### United States Patent and Trademark Office

UNITED STATES DEPART United States Patent and Trademar Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

U.S. APPLICATION NUMBER NO.

WOODCOCK WASHBURN LLP

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/541,527

ONE LIBERTY PLACE, 46TH FLOOR

Sebastien Rose

CEPF-0007

INTERNATIONAL APPLICATION NO.

PCT/IB04/00002

I.A. FILING DATE

PRIORITY DATE

01/08/2004

01/13/2003

RECEIVED

JAN 1 2 2006

**CONFIRMATION NO. 1480** 

**371 FORMALITIES LETTER** 

OC000000017798075\*

Woodcock Washburn

Date Mailed: 01/06/2006

1650 MARKET STREET

PHILADELPHIA, PA 19103

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 07/07/2005
- Copy of the International Search Report filed on 07/07/2005
- Request for Immediate Examination filed on 07/07/2005
- U.S. Basic National Fees filed on 07/07/2005
- Priority Documents filed on 07/07/2005
- Power of Attorney filed on 07/07/2005

RECEIVED

JAN 1 2 2006

**DOCKET DEPT** WWKMN

The applicant needs to satisfy supplemental fees problems indicated below.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$1360 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$1490 for a Large Entity:

- \$130 Surcharge.
- Total additional claim fee(s) for this application is \$ 1360
  - \$1000 for 20 total claims over 20.
  - \$360 for multiple dependent claim surchare.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

SHELBY J VIGIL

Telephone: (703) 308-9140 EXT 224

### PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY, DOCKET NO.
10/541,527	PCT/IB04/00002	CEPF-0007

FORM PCT/DO/EO/905 (371 Formalities Notice)

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